

REMARKS/ARGUMENTS

The Office Action mailed February 22, 2005 has been carefully considered.

Reconsideration in view of the following remarks is respectfully requested.

Claims 1-17 are currently pending. Claims 1-17 have been rejected. Claims 1 and 16 have been amended to further particularly point out and distinctly claim subject matter regarded as the invention as suggested by the Examiner. Support for these changes may be found in the specification on pages 9, lines 21-22. The text of claims 2-4, 6-15, and 17 are unchanged, but their meaning is changed because they depend from amended claims. No new matter has been added.

The 35 U.S.C. § 112, First Paragraph Rejection

Claims 1-15 and 17 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This objection is respectfully traversed. The Office Action states that the “amendment of the claims to recite ‘wetting agent solution’ has introduced new matter to the scope of the claims that is not supported by applicant’s disclosure as originally filed. ... The text of the specification that applicant is referring to for support on page 19 is actually a step in the process of preparing the composition wherein the cross-linked gelatin is soaked with solution of the wetting agent, the followed by the step of drying to obtain the final composition. Therefore, the final composition is not containing the solution of wetting agent as applicant recited in the claims.” Applicant respectfully disagrees for the reasons, among others, discussed below.

MPEP §2163.04 states that the Examiner must “establish a prima facie case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. … When appropriate, suggest amendments to the claims which can be supported by the application’s written description.” The Examiner has not established a prima facie case nor has the Examiner provided any suggested amendments.

Furthermore, Applicant respectfully maintains that composition claims are not required to only be directed to the final composition, but can apply to a mixture of compounds¹. This composition has been clearly set forth in the specification and in the claims. Thus, a person skilled in the art at the time the application was filed would have recognized that the composition comprised both the wetting agent solution and cross-linked gelatin.

As such, Applicant respectfully maintains that the 35 U.S.C. 112, first paragraph, rejection should be withdrawn.

The 35 U.S.C. § 112, Second Paragraph Rejection

Claims 1-15 and 17 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter applicant regards as the invention. This objection is respectfully traversed.

Specifically, the Office Action states that “claims 1 and 5 [recite] a broad range or limitation together with a narrow range or limitation and falls within the broad range or

limitation (in the same claim) is considered indefinite.” Application respectfully disagrees. MPEP §2173.05(h) provides that “double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. … The mere fact that a compound may be embraced by more than one member of a Markush group recited in the claim does not necessarily render the scope of the claim unclear.” Accordingly, it is respectfully asserted that this rejection under USC § 112, second paragraph, is inappropriate and should be withdrawn.

Double Patenting Rejection

Claim 16 stands rejected under the judicially created doctrine of obviousness-type double patenting. These rejections are respectfully traversed.

“In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is -- does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? … Obviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patently distinct** from the subject matter claimed in a commonly owned patent.” MPEP § 804(II)(B)(1).

The Office Action states that:

“the examiner position is that the kit of claim 16 is an obvious variant of the system claimed by all of the conflicted claims of the issued patents and copending application. The present claim 16 is directed to kit comprising pledget, syringe and wetting agent, and the system of the issued patent comprises compartment containing pledget and a hydrating fluid. Syringe means ‘an instrument for injection or withdrawing fluid’, according to WEBSTER II, and that reads on the compartment containing the pledget claimed in US ‘192.’”

¹ See M.P.E.P. §2163.

Applicant respectfully disagrees. The Office Action did not address all the arguments made by Applicant, but merely responded to Applicant's argument with respect to US '192. To further prosecution of this application, Applicant will assume the same response applies to all of Applicant's previous arguments.

Furthermore, the Office Action was vague in its rejection. Not only must a showing be made for the rejection to be legal, but it must be made in a manner which gives Applicant an opportunity to address it directly. The vague reference to the cited arts cannot be meaningfully rebutted by Applicant and Applicant hereby formally requests that the Examiner set forth where each and every element of each and every claim rejected is found in the prior art reference. In any event, Applicant will attempt to respond to the vague rejection in the Office Action.

Additionally, Applicants respectfully request that the Examiner carefully read the '192 patent, '328 patent, '151 patent, '734 patent, '735 patent, and '752 application to more fully understand the inventions. Otherwise, it is respectfully requested that this rejection be withdrawn.

A. Claim 16 stands "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claim 8 of U.S. Patent No. 6,162,192, now on US '192, in view of US 6,063,061 for Wallace et. al." This rejection is respectfully traversed.

The office action states:

"The US '192 patent claims are directed to composition comprising syringe and pledget and hydrating agent. The difference between the present claims and the previously issued conflicted claim is that the issued claim does not teach the sterilized packaged composition, or the pledget made of crosslinked gelatin."

Claim 8 of the ‘192 patent reads:

“A system for facilitating hemostasis of a puncture in the wall of a blood vessel, the system comprising:

a tract dilator having a lumen for allowing the tract dilator to be passed over a guidewire;

an introducer having a lumen for allowing the introducer to be passed over the guidewire, the introducer lumen including a staging chamber configured to receive an absorbable sponge pledge and a delivery chamber;

a plunger having a lumen for allowing the plunger to be passed over the guidewire, the plunger insertable into the introducer for ejection of the pledge from the delivery chamber into a patient to seal a puncture in a blood vessel wall;

a proximal end of the introducer having a luer fitting for connection to a syringe for hydrating the absorbable sponge pledge and injecting the pledge from the introducer into the delivery chamber.”

Applicant is still unclear why the Examiner would assert an obviousness-type double patenting rejection between Claim 16 of the claimed invention and Claim 8 of the ‘192 patent. Claim 16 is clearly patentably distinct from the subject matter claimed in ‘192. Claim 8 of the ‘192 patent does not claim a “composition comprising syringe and pledge and hydrating agent” as alleged by the Examiner.

Furthermore, the Office Action improperly equates the syringe with the “compartment containing pledge and a hydrating fluid” of the ‘192 patent. As stated by the Examiner, the definition for a syringe is “an instrument for injection or withdrawing **fluid**” and not a **pledge**. Thus the syringe cannot be equated with the “compartment containing a pledge and a hydrating fluid.”

Thus, it is respectfully requested that this rejection be withdrawn.

B. Claim 16 stands “rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 6-18 of U.S. Patent No. 6,200,328, now on US ‘328, in view of US 6,063,061 for Wallace et. al.” Claims 6 and 9 are independent claims. This rejection is respectfully traversed.

The office action states that “US ‘328 claims are direction to a system, reads on kit, comprising pledge and hydrating fluid and syringe.”

Applicant is still unclear why the Examiner would assert an obviousness-type double patenting between Claim 16 of the claimed invention and Claims 6-18 of the ‘328 patent. Claim 16 is patentably distinct from the subject matter claimed in ‘328. Furthermore, the Office Action improperly equates the syringe with the “compartment containing pledge and a hydrating fluid” of the ‘328 patent. As stated by the Examiner, the definition for a syringe is “an instrument for injection or withdrawing fluid” and not a **pledge**. Thus the syringe cannot be equated with the “compartment containing a pledge and a hydrating fluid.” It is respectfully requested that this rejection be withdrawn.

C. Claim 16 stands “rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,440,151, now on US ‘151, in view of US 6,063,061 for Wallace et. al.” Claims 1 and 12 are independent claims. This rejection is respectfully traversed.

The office action states that “US ‘151 claims are directed to a system, reads on kit, comprising pledge and hydrating fluid and syringe.”

Applicant is still unclear why the Examiner would assert an obviousness-type double patenting between Claim 16 of the claimed invention and Claims 1-5, 12-16 of the ‘151 patent.

It is clear that Claim 16 is patentably distinct from the subject matter claimed in '151. In fact, independent Claims 1 and 12 of the '151 patent do not even claim a "system, reads on kit, comprising pledget and hydrating fluid and syringe" as alleged by the Examiner. Furthermore, the Office Action improperly equates the syringe with the "compartment containing pledget and a hydrating fluid" of the '151 patent. As stated by the Examiner, the definition for a syringe is "an instrument for injection or withdrawing **fluid**" and not a **pledget**. Thus the syringe cannot be equated with the "compartment containing a pledget and a hydrating fluid." It is respectfully requested that this rejection be withdrawn.

D. Claim 16 stands "rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 1-5, 12-16 of U.S. Patent No. 6,527,734, now on US '734, in view of US 6,063,061 for Wallace et. al." Claim 1 is an independent claim. This rejection is respectfully traversed.

The office action states that "US '734 claims are directed to a system, reads on kit, comprising pledget and hydrating fluid and syringe."

Applicant is still unclear why the Examiner would assert an obviousness-type double patenting between Claim 16 of the claimed invention and Claims 1-5, 12-16 of the '734 patent. It is clear that Claim 16 is patentably distinct from the subject matter claimed in '734. In fact, independent Claim 1 of the '734 patent does not even claim a "system, reads on kit, comprising pledget and hydrating fluid and syringe" as alleged by the Examiner. Furthermore, the Office Action improperly equates the syringe with the "compartment containing pledget and a hydrating fluid" of the '734 patent. As stated by the Examiner, the definition for a syringe is "an instrument for injection or withdrawing **fluid**" and not a **pledget**. Thus the syringe cannot be

equated with the “compartment containing a pledget and a hydrating fluid.” It is respectfully requested that this rejection be withdrawn.

E. Claim 16 stands “rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 8-22 of U.S. Patent No. 6,540,735, now on US ‘735, in view of US 6,063,061 for Wallace et. al.” Claims 8, 15, 17 are independent claims. This rejection is respectfully traversed.

The office action states that “US ‘735 claims are directed to system, reads on kit, comprising pledget and hydrating fluid and syringe.”

Applicant is still unclear why the Examiner would assert an obviousness-type double patenting between Claim 16 of the claimed invention and Claims 8-22 of the ‘735 patent. It is clear that Claim 16 is patentably distinct from the subject matter claimed in ‘735. In fact, independent Claims 8, 15, and 17 of the ‘735 patent does not even claim a “system, reads on kit, comprising pledget and hydrating fluid and syringe” as alleged by the Examiner. Furthermore, the Office Action improperly equates the syringe with the “compartment containing pledget and a hydrating fluid” of the ‘735 patent. As stated by the Examiner, the definition for a syringe is “an instrument for injection or withdrawing **fluid**” and not a **pledget**. Thus the syringe cannot be equated with the “compartment containing a pledget and a hydrating fluid.” It is respectfully requested that this rejection be withdrawn.

F. Claim 16 stands “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being [allegedly] unpatentable over claims 8-14, 17-22 of copending Application No. 10/366,752 in view of US 6,063,061 for Wallace et. al.” Claims 1-

22 of copending Application 10/366,752 were cancelled thus rendering this rejection moot.

It is respectfully requested that this rejection be withdrawn.

Claims 1 and 16 – The First 35 USC §102 Rejection

Claims 1, 15, and 16 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by US 6,063,061 (Wallace). Claims 1 and 16 are independent claims. This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.²

The office action states:

“the present claims are directed to a composition and kit, and all the elements are disclosed by the reference, i.e. cross-linked gelatin and plasticizer, which reads on the polymer cited by applicant as a wetting agent. The reference anticipates the present claims, in absence of support to the wetting agent solution. The expression ‘comprising’ of the claims language permits the presence of the hydrated gel and the container including the hydrating agent. The dried gel disclosed by the reference reads on the pledget since applicant did not define the pledget”

Applicant respectfully disagrees. Claims 1 and 16 have been amended to further clarify the invention by stating that the wetting agent solution is incorporated into the cross-linked gelatin and that the pledget consists of the wetting agent incorporated into the cross-linked gelatin, respectively. This is further stated and supported throughout the specification, such as on page 9, lines 21-22.

² Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As stated previously, Wallace discloses the use of “cross-linked gels . . . applied to target sites in a patient’s body by extruding the gel through an orifice at the target site” (Abstract). Wallace further provides for “kits comprising any of the hydrated or non-hydrated gel materials. . . When the gel material is non-hydrated, the kit may optionally include a separate container with a suitable aqueous buffer for hydration.” (col. 8, lines 22-36). Thus, Wallace does not teach or disclose the use of a pledge which has the wetting agent incorporated into the cross-linked gelatin as claimed in Claims 1 and 16, rather the “aqueous buffer for hydration” of Wallace is contained in a separate container from the gel.

Accordingly, since each and every element as set forth in Claims 1 and 16 are not found, either expressly or inherently described, in Wallace, it can not be said to anticipate the present invention. Thus, it is respectfully requested that this rejection be withdrawn.

Claims 1 and 5 – The Second 35 USC §102 Rejection

Claims 1-6, 8-13, 15, and 17 stand rejected under 35 U.S.C. 102(e) as being allegedly anticipated by US PGPB 2002/0042378 (the ‘378 application). Claims 1 and 5 are independent claims. This rejection is respectfully traversed.

The office action states:

“the claims are directed to composition and all the elements of the composition are disclosed by the reference. Applicant recites the wetting agents including polymer, hence, the non-cross linked polymer disclosed by the reference reads on the wetting agent. The reference disclosed on page 4, paragraph 0035 that the cross-linked gelatin is mixed with solution of non cross-linked polymer and then dried and that reads on the scope of the claims, absent support to the wetting agent solution in the final composition.”

Applicants respectfully disagree for the reasons, among others, discussed below.

As stated previously, Claims 1 and 5 provide for the use of a wetting agent **solution**, which support can be found in the specification as discussed above. Furthermore, as argued previously, the ‘378 application states that the “cross-linked polymer is dispersed in a dried

matrix of the non cross-linked polymer.” (page 1, 0012). This is further stated throughout the specification of the ‘378 application and also in Claim 1 which states “the cross-linked polymer is dispersed in a **dried** matrix of the non-cross-linked polymer” and Claim 2 which states “**dry**, cross-linked gelatin polymer particles dispersed in the dry non-cross-linked gelatin matrix.” (page 7, Claim 1 and 2).

Thus, the ‘378 application teaches dispersing the non cross-linked polymer with the cross-linked polymer when both are in the dry phases and does not teach “a sufficient amount of a wetting agent **solution**” as provided for in Claim 1 and similarly in Claim 5.

Accordingly, since each and every element as set forth in Claims 1 and 5 are not found, either expressly or inherently described, in the ‘378 application, it can not be said to anticipate the present invention. Thus, it is respectfully requested that this rejection be withdrawn.

Dependent Claims

The argument set forth above is equally applicable here. The base claims being allowable, the dependent claims must also be allowable.

The Office Action states that Claims 7 and 14 stand rejected under 35 USC 103(a) as being unpatentable over PGPB ‘378 and that since “applicant has failed to traverse the rejection, the response is considered to be acquiescence to the position taken by the Examiner.” This is respectfully traversed as applicant has continually stated and as provided for in the MPEP, the argument for the base claims are equally applicable to dependent Claims 7 and 14 and should the base claims be allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

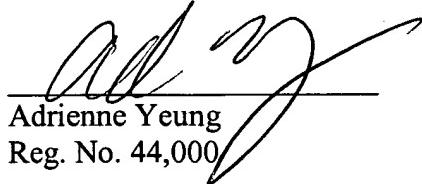
It is believed that this Response places the above-identified patent application into condition for allowance. Early favorable consideration of this application is earnestly solicited.

Applicant and Applicant's Attorney thanks the Examiner for her consideration and attempts to help with the prosecution of this application. It is again respectfully requested that the Examiner call the Applicant's Attorney for an interview to expedite the prosecution of this application should a Notice of Allowance not result from this Amendment and Response.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Please charge any additional required fee or credit any overpayment not otherwise paid or credited to our deposit account No. 50-1698.

Respectfully submitted,
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Dated: April 27, 2004


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